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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/551,645 04/18/00 HAHN

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EXAMINER

GRASER, J

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

10/19/01

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/551,645

Applicant(s)
Hahn

Examiner
Jennifer Graser

Art Unit
1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Election/Amendment B, 8/6/01.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above, claim(s) 1-3 and 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

Art Unit: 1645

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group II, claim 4, in Paper No. 7 is acknowledged. The traversal is on the ground(s) that a literature search for the elected group would encompass the subject matter of the remaining claims. This is not found persuasive because Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the epitope of Group I can be used for methods other than in the research of cellular and molecular biology, i.e., it could be used in a detection assay as a diagnostic reagent or as an immunogen. Groups I and II are biologically, chemically and structurally different products and therefore are patentably distinct. A literature search for the antibody of Group II would not be coextensive with the other groups. It would place a serious burden on the Examiner to examine all of the claims.

The requirement is still deemed proper and is therefore made **FINAL**. Claims 1-3 and 5 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1645

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is vague and confusing because it fails to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The wording of the claim is very confusing making it unclear whether it is an antibody or a protein or something else which is being claimed. If Applicant wishes to claim a "monoclonal antibody or polyclonal antibody which specifically binds to an SRTAG having the amino acid sequence of SEQ ID No:1", then that is how it should be claimed. The characterization of the tagged protein in the last three lines of the claim serves only to distract from the invention. These lines mislead one to think that perhaps an oligonucleotide or a fusion product, instead of an antibody, is the actual invention. Further, "a monoclonal antibody or polyclonal antibody to the SRTAG...as an epitope for any tagged protein, wherein said tagged protein is detected by a mouse monoclonal antibody..." is highly confusing. The characterization of the tagged protein beyond that it has the amino acid sequence of SEQ ID No:1 only serves to confuse the claim. There are serious language problems with this claim. The claims should also specify that the antibody "specifically binds" to the protein. *Appropriate correction is required.*

Art Unit: 1645

Further, it appears that the "polyclonal antibody" is a product of nature because the claim does not state that the polyclonal antibody is purified or isolated.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by (Hahn et al. Gene, 1993, 133:129-133).

Hahn et al disclose an amino acid sequence which is 100% identical to Applicant's SEQ ID NO:1 and a nucleic acid sequence which is 100% identical to Applicant's SEQ ID NO:2. Monoclonal antibodies to the crystalline surface layer protein (SLP) of *Rickettsia typhi* were made. Additionally, the epitope recognized by one of the monoclonal antibodies (SRT10, IgG2a) to 10 amino acids residues of SLP was determined. This monoclonal antibody which recognizes SRT10 anticipates the claim. The binding specificities of the claimed antibody and that of Hahn are the same.

6. Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Carl et al. (US 5,783,441).

Carl et al disclose a peptide which differs by only one amino acid from Applicant's SEQ ID NO:1. It is disclosed that monoclonal antibodies directed against different linear epitopes

Art Unit: 1645

present on the rickettsial crystalline surface layer protein antigen (SPA) were made. This would include the epitope set forth in SEQ ID NO:1.

Prior Art Made of Record:

7. Hackstadt et al. Infection and Immunity. Jan. 1992, 159-165, Vol. 60, No. 1 (abstract only at this time). Hackstadt et al teach a peptide which is 100% identical to Applicant's SEQ ID NO:1. The reference disclose proteins from *Rickettsia* which are 120-kDa and 32-kDa in size. Monoclonal antibodies to these proteins were made.

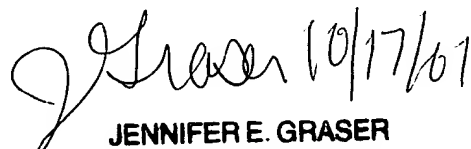
Ching et al. Molecular Immunology. 1992. 29: 95-102 "Mapping of monoclonal antibody binding sites on CNBr fragments of the S-layer protein antigens of *Rickettsia typhi* and *Rickettsia prowazekii*". Ching et al disclose a peptide which is 100% identical to Applicant's SEQ ID NO:1.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 308-4242 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (703) 308-1742. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


JENNIFER E. GRASER
PRIMARY EXAMINER